I. Introduction

With the cancellation herein without prejudice of claims 9 and 59, claims 1-8, 10-58 and 59-82 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

II. Objection to Drawings

As regards the objections to the drawings indicated in paragraph 1 of the Office Action, it is believed and respectfully submitted that the attached replacement sheets of drawings obviate these objections, and withdrawal of these objections is therefore respectfully requested. No new matter has been added.

III. Objection to Specification

Applicant has amended the Specification as requested by the Examiner so as to update the patent application data. No new matter has been added. Applicant respectfully requests that the objection be withdrawn.

IV. Objection to Claim 74

Applicant has amended claim 74 as requested by the Examiner. Applicant respectfully requests that the objection be withdrawn.

V. Rejection of Claims 2, 16, 21, 28, 31, 55, 57, 74 and 82 Under 35 U.S.C. §112

Applicant has amended claims 16, 21 and 74 without prejudice so as to provide antecedent basis for the terms noted by the examiner. In addition, Applicant has amended claims 2, 28, 31, 55, 57 and 82, without prejudice so as to recite that the shaft is sized and configured for one of endoscopic (claims 2, 31 and 57) or proctoscopic or anoscopic (claims 28, 55 and 82) insertion into a patient's body.

Applicant respectfully maintains that these claims comply with all of the requirements of 35 U.S.C. §112, second paragraph, and requests that the rejections be withdrawn.

VI. Rejection of Claims 29-32, 35-64 and 67-82 Under 35 U.S.C. § 102(b)

Claims 29-32, 35-64 and 67-82 were rejected under 35 U.S.C. 102(b) as anticipated by International Patent Publication No. WO93/15648 ("Wilk et al."). Applicant respectfully submits that Wilk et al. does not anticipate the present claims for the following reasons. Claim 59 has been canceled herein without prejudice, therefore Applicant respectfully maintains that the rejection of claim 59 is moot.

Claim 29 relates to a surgical system that includes a shaft having a distal end. Claim 29 has been amended herein without prejudice to recite that the shaft is sealed so as to be sterilizable for re-use. Support for this amendment can be found, for instance at page 21, lines 22-23, of the Specification which states that "because ... the shaft 12... may be sterilizable, [it] can be used more than once and on more than one patient." Claim 29 recites that the surgical system includes an image capture device configured to receive image data from the distal end of the shaft. Claim 29 recites that the surgical system includes a light source configured to provide light at the distal end of the shaft.

Claim 56 relates to a surgical system including a shaft having a proximal end and a distal end. Claim 56 has been amended herein without prejudice to recite that the shaft is sealed so as to be sterilizable for re-use. Support for this amendment is set forth above in connection with claim 29. Claim 56 recites that the surgical system includes an image capture device configured to receive image data from the distal end of the shaft. Claim 56 recites that the surgical system includes a light source configured to provide light at the distal end of the shaft. Claim 56 recites that the surgical system includes a control module coupled to the proximal end of the shaft. Claim 56 recites that the surgical system includes a power module coupled to the control module, the power module configured to drive at least one drivable component housed in at least one of the shaft, the control module and the power module. Claim 56 recites that the surgical system includes at least one power

source integrally housed in at least one of the shaft, the control module and the power module.

Wilk et al. purport to describe "an endoscope with a disposable insertion member." Title. Wilk et al. state that "Fig. 1 [illustrates] an endoscope [that] comprises a hand held control module 12 and a disposable insertion tube 14 provided with a plurality of ducts or channels 16 extending longitudinally through the insertion tube to a distal end 18 thereof." Page 7, lines 5-8. Wilk et al. describe that "insertion tube 14 is slid over optical guide member 20 and attached to control module 12." Page 8, lines 33-35.

It is respectfully submitted that Wilk et al. do not anticipate claims 29 and 56 for at least the reason that Wilk et al. do not disclose, or even suggest, all of the features recited in claims 29 and 56. For example, Wilk et al. do not disclose, or even suggest, a shaft that is sealed so as to be sterilizable for re-use as recited in claims 29 and 56. The Specification states at page 5, lines 6-8, that "[a]ccording to one embodiment, the shaft 12 includes a tubular sheath 13, which may include a coating or other sealing arrangement to provide a fluid-tight seal between an interior region of the shaft 12 and the environment." The Specification also states at page 5, lines 8-10, that "[t]he sheath 13 may be formed of a tissue-compatible, sterilizable elastomeric material [and] preferably, the sheath 13 may be formed of a material that is autoclavable." The Specification also states at page 5, lines 11-15, that "[f]or instance, the sheath 13 may be formed of a material such as Teflon™ (i.e., a fluoropolymer, e.g., polytetrafluoroethylene — "PTFE"), silicone, a Teflon™/silicone combination, such as, for example, SIL-KORE™ (made by W.L. Gore & Associates), "EPTFE", e.g., expanded teflon, etc." In describing the disadvantages of conventional endoscopic arrangements, the Specification states at page 21, lines 13-16, that "[c]onventional endoscopes typically can not be sterilized prior to use within a patient because the materials employed in the manufacture of conventional endoscopes are not sterilizable, and because conventional endoscope are typically not adequately sealed to withstand a sterilization process." Emphasis added. In describing the advantages of the present invention, the Specification states at page 21, lines 21-26, that "because ... the shaft 12... may be sterilizable, [it] can be used more than once and on more than one patient, providing significant cost savings as

compared to conventional endoscope systems that must be discarded after one use."

Wilk et al., on the other hand, describe at page 9, lines 1-4, that "[u]pon the termination of the operation, insertion tube 14 and optical guide member 20 are withdrawn from the patient [,] insertion tube 14 is then detached from control module 12 and optical guide member 20 is removed from insertion tube 14." Wilk et al. state at page 9, lines 5-7, that "[i]nsertion tube 14 is discarded, while control module 12 and optical guide member 20 are ready for immediate use with another disposable insertion tube 14." Importantly, Wilk et al. state at page 9, lines 7-10, that **"[t]here is no need to subject optical guide member 20 to sterilizing and cleaning operations which may damage the optical guide and eventually wear it down**." Emphasis added. Thus, irrespective of whether the insertion tube 14 or the optical guide member 20 could be considered to be a shaft within the meaning of the claims, Wilk et al. readily admit that neither the insertion tube 14, which is discarded after a single use, nor the optical guide member 20, which is not designed so as to be sterilizable (but instead is covered by the insertion tube 14 so as to avoid the need for sterilizing the optical guide member 20 for re-use), satisfies the feature of a shaft that is sealed so as to be sterilizable for re-use. In this manner, the arrangement of Wilk et al. suffers from precisely a disadvantage that is addressed by systems hereof.

The Office Action states that "all components of Wilk et al. are 'sterilizable' and 'autoclavable' since everything is 'sterilizable' and 'autoclavable'." Office Action at page 4. This statement is simply untrue. As set forth above, the Specification states at page 21, lines 13-16, that "[c]onventional endoscopes typically can not be sterilized prior to use within a patient because the materials employed in the manufacture of conventional endoscopes are not sterilizable, and because conventional endoscope are typically not adequately sealed to withstand a sterilization process." Emphasis added. Wilk et al. actually support Applicant's contention on this point because Wilk et al. admit that subjecting the optical guide member 20 to sterilization or other cleaning operation may damage the optical guide and eventually wear it down, and because the specific purpose of the insertion tube 14 in Wilk et al. is to cover the optical guide member 20 during use and thereby avoid subjecting the optical guide member 20 to a sterilization or other cleaning process.

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Wilk et al. does not anticipate claims 29 and 56, because Wilk et al. does not disclose, or even suggest, all of the features recited in these claims.

In summary, it is respectfully submitted that Wilk et al. do not anticipate claims 29 and 56. As for claims 30-32, 35-55, 57, 58, 60-64 and 67-82, each of which ultimately depend from and include all of the limitations of a respective one of independent claims 29 and 56, it is respectfully submitted that Wilk et al. do not anticipate these dependent claims for at least the same reasons given above in support of the patentability of their respective independent claims.

VII. Rejection of Claims 1-28, 33, 34, 65 and 66 Under 35 U.S.C. § 103(a)

Claims 1-28, 33, 34, 65 and 66 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Wilk et al. in view of Kanno et al. It is respectfully submitted that the combination of Wilk et al. and Kanno et al. does not render obvious the present claims herein for the following reasons. Claim 9 has been canceled herein without prejudice, therefore Applicant respectfully maintains that the rejection of claim 9 is moot.

Claim 1 relates to a surgical system. Claim 1 recites that the surgical system includes a shaft having a distal end. Claim 1 has been amended herein without prejudice to recite that the shaft is sealed so as to be sterilizable for re-use. Support for this amendment can be found, for instance at page 21, lines 22-23, of the Specification which states that "because ... the shaft 12... may be sterilizable, [it] can be used more than once and on more than one patient." Claim 1 also recites that the surgical system includes an image capture device configured to receive image data from the distal end of the shaft. Claim 1 also recites that the surgical

system includes a light source configured to provide light at the distal end of the shaft, wherein the light source is a light-emitting diode.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

It is respectfully submitted that Wilk et al. do not render unpatentable claim 1 for at least the reason that Wilk et al. do not disclose, or even suggest, all of the features recited in claim 1. For example, Wilk et al. do not disclose, or even suggest, a shaft that is sealed so as to be sterilizable for re-use as recited in claims 1, for at least those reasons set forth above in connection with the patentability of claims 29 and 56. Generally, irrespective of whether the insertion tube 14 or the optical guide member could be considered to be a shaft within the meaning of the claims, Wilk et al. readily admit that neither the insertion tube 14, which is discarded after a single use, nor the optical guide member, which is not designed so as to be sterilizable (but instead is covered by the insertion tube 14 so as to avoid the need for sterilizing the optical guide member 20 for re-use), satisfies the feature of a shaft that is sealed so as to be sterilizable for re-use. Kanno et al. are not relied on to disclose or suggest, and do not disclose or suggest, those features of claim 1 not disclosed or suggested by Wilk et al. For instance, Kanno et al. are not relied on to disclose or suggest, and do not disclose or suggest, a shaft that is sealed so as to be sterilizable for re-use, which as set forth more fully above, is not disclosed or suggested by Wilk et al.

For at least the same reasons, the combination of Wilk et al. and Kanno et al. do not disclose, or even suggest, all of the limitations of claims 2-8, 10-

28, 33, 34, 65 and 66, because, by virtue of their dependency on a respective one of independent claims 1, 29 and 56, each one of these dependent claims includes the feature of a shaft that is sealed so as to be sterilizable for re-use. Therefore, it is respectfully maintained that claims 2-8, 10-28, 33, 34, 65 and 66 are also allowable for at least the same reasons that claim 1, 29 and 56 are allowable as more fully set forth above. Withdrawal of this rejection is therefore respectfully requested.

VIII. Conclusion

Applicant respectfully submits that the pending claims are in condition for allowance and requests that such action be taken. If for any reason the Examiner believes that prosecution of this application would be advanced by contact with the Applicant's attorney, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,

KENYON & KENYON

Date: August 31, 2005 By: _____

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AMENDMENTS TO THE DRAWINGS:

The attached ten (10) sheets of ink drawings, including Figures 1 to 10, replace the drawings, including Figures 1 to 10, submitted on September 30, 2003. No new matter has been added.

Attachment: Ten (10) Replacement Sheets